## REMARKS

Claims 34-44 were rejected under 35 U.S.C. §112, first paragraph, on two grounds. The first ground for failure to comply with the written description requirement, and the second ground was for failure to comply with the enablement requirement. Applicant believes that both grounds of rejection should be withdrawn in view of the following remarks.

Regarding the written description requirement, the Examiner is again referred to the description of the invention at page 20, line 10 to page 21, line 15; page 31, line 18 to page 32 line 19; page 33, lines 8-10; page 45, lines 1-30; page 46, lines 3-16; page 47, line 1 to page 48, line 29; page 50, lines 18-21; page 52, lines 7-11; Example 18 on page 53; and Example 19 on page 55. Note that the above-mentioned citations refer to both generic and specific disclosures, including the treatment of organs to improve function, and the formation of an artery. Once the claims are considered, it is apparent that such generic and specific disclosure is pertinent to the enablement of the claimed invention and thus must be read and evaluated by the Examiner.

The Examiner quoted the paragraph at page 47, lines 1-6 of the specification and erroneously implied that such paragraph is the only relevant paragraph regarding the claimed invention. Such selective reading of the specification ignores the next paragraph at page 47, lines 7-21 which provides further disclosure involving the insertion of a growth factor into or around an organ to rejuvenate and restore the fitness and function of such organ. Obviously, these two paragraphs must be read in conjunction with each other. In addition, the Examiner must read and consider other specific disclosure at page 52, lines 7-11 where organ sub-structures such as Islet cells are mentioned. The Examiner must also read and consider the above-cited disclosure pertinent to the

formation of arteries because such formation is contained in the claims.

From the foregoing remarks, it is evident that the Examiner has failed to consider the disclosure provided by Applicant's specification and cited above, as a whole, in determining compliance with the written description requirement of the statute. The appropriate factual determination is whether the instant specification conveys to one skilled in the art that Applicant invented the claimed subject matter. The Examiner erroneously restricted the factual determination to the elected species of growth factor, claimed organ, and type of lost function of such organ thereby ignoring those portions of the specification describing a broader generic invention, the use of other growth factor species, such as genes, and the treatment of other organs. Applicant is entitled to have the entire disclosure considered in determining compliance with 35 U.S.C. §112, first paragraph. See In re Anderson, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973); In re Johnson and Farnham, 555 F.2d 1008, 194 USPQ 187, 195 (CCPA 1977). The selective, limited evaluation performed by the Examiner is clearly erroneous and fails to comport with current law. It is apparent that the Examiner's evaluation of the specification is intended to be so improperly limited in view of the Examiner's statements at page 3 of the present Office Action. The Examiner's flawed reading of the specification has thereby led to a flawed conclusion. Upon a reasonable and complete reading of the specification, it will be evident to one skilled in the art that the scope of the claimed subject matter is fully supported by the above-referenced disclosures.

Claims 34-44 were also rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

Based upon the above-quoted portions of the specification, it is clear that Applicant has broadly disclosed a method of rejuvenating and restoring function of a human pancreas by locally

inserting a growth factor at the pancreas to grow Islets of Langerhans. Moreover specific claims to cellular growth factors would be understood by one skilled in the art to be covered by such disclosure. As should be appreciated by the Examiner, the scope of the present claims is clearly within the scope of the disclosure; and thus Applicant is entitled to have the entire disclosure evaluated regarding enablement. Likewise, disclosures of other species of growth factors and the treatment of other organs must be considered in any fair, reasonable evaluation of enablement. However, the Examiner has erroneously failed to consider such disclosure. Once the disclosure has been correctly considered in its entirety, rather than in a restrictive and selective manner, it is clear that enablement is present.

It is important to note that the first paragraph of the statute requires nothing more than objective enablement, and it is of no importance whether such teaching is set forth by use of illustrative examples or by broad terminology. As a general matter, an application disclosure, which contains a teaching of how to make and use the invention in terms which correspond in scope to those used in describing the invention sought to be patented is considered to be in compliance with the enabling requirement of the statue. In re Marzocchi, 58 CCPA 1069, 439 F.2d 220, 169 USPQ 367, 369-370 (1971). Further, "Section 112 does not require that a specification convince persons skilled in the art that the assertions therein are correct." (emphasis added). In re Robins, supra.

The Examiner's improperly limited evaluation disregards the genus growth factors, gene growth factor species, and the treatment of other organs. By not considering such disclosure, the Examiner has committed error and clearly has not followed the tenets of Anderson and Johnson and Farnham.

The disclosed administration techniques were well established in the medical art prior to

Applicant's invention and thus must be considered in any reasonable evaluation of enablement. Moreover, cells, including stem cells, were well known and characterized prior to Applicant's claimed invention. Stem cell banks were created as early as the 1950's, thereby illustrating that those skilled in the medical art were familiar with harvesting, handling, culturing, preserving, separating, and storing, etc. such stem cells. Caplan 1991 reported culturing human bone marrow and isolating mesenchymal stem cells. Dr. Elia's contribution to the medical art as it pertains to the claims, however, was that growth of new arteries to effect organ repair, including the brain and heart, could be accomplished through use of a new combination of old administration techniques and old growth factors, including cellular materials. Knowledge of the above facts, in combination with Applicant's entire disclosure, compels the conclusion that one skilled in the medical art could read Applicant's disclosure of the invention and the claims in issue and reasonably determine that such disclosure would enable one skilled in the art to make and use the claimed invention without recourse to more than routine experimentation.

Once the relevant materials and administration techniques set forth in Applicant's specification are properly considered in their entirety, Applicant believes that there should be no question that one skilled in the medical art is enabled to make and use the claimed invention. This conclusion is reinforced by the fact that the materials and administration techniques, but not the inventive result, were well known when the instant application was filed. MPEP Section 2164 states that the purpose of the enablement requirement is to describe the claimed invention in such terms to permit one skilled in the art to make and use the invention. Such Section cautions that detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. MPEP

Section 2164.01 states that

> A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F2d. 660, 661, 18 USPQ 2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F2d. 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986) cert denied, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F2d. 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

Applicant believes that the above caution is especially relevant to the instant factual situation when it is considered that a skilled person in the art pertaining to the claimed invention must be and is of a high skill level because many years of education and training are required to enter the field. In the outstanding Office Action, the Examiner has erroneously ignored, and apparently not considered, the high skill level in the art when making an evaluation of enablement. Such error regarding the skill level pertaining to the field of the claimed invention is especially egregious when it is considered that the administration techniques and administered materials are separately well known in the art. What is not known is the remarkable effect obtained by such new combination. In any event, it is evident that a high level of skill is required to practice in the field pertaining to the invention and that the administration techniques and materials are separately old and well known. Thus, Applicant submits that the instant disclosure, when reasonably read and understood by a highly skilled medical person is clearly sufficient to enable such person to make and use the claimed invention.

In summary, Applicant submits that the Examiner has apparently failed to comprehend that Applicant has used old and routine administration techniques and old materials to achieve a new result, namely, the rejuvenation and restoration of pancreas function. Inasmuch as the claimed administration techniques and materials were well known to those in the art, the highly skilled person in the medical art to which the instant invention pertains would not require an extensive,

detailed description of such old elements of the invention and thus would readily be enabled to make and use the claimed invention once directed to the administration techniques and materials by Applicant's specification. See Buchner, supra; Hybritech, supra; and Lindemann Maschinenfabrik, supra. It is noted that the Examiner has not taken issue with the fact that these administration techniques and materials were known as of the filing date of the instant application.

The Examiner, in an apparent attempt to take issue with the above demonstrated enabling nature of the disclosure and thus to establish a *prima facie* case of lack of enablement, recited and very briefly addressed seven of the eight factors mentioned by In re Wands, 8 USPQ2d. 1400 (Fed. Cir. 1988). Applicant does not believe that such non-detailed recitation has provided the requisite evidence to support and establish a *prima facie* case of non-enablement for the following reasons.

As pointed out above, Applicant believes that the Examiner has failed to even consider and then to accord proper weight to the Wands factor relating to the skill level in the art. Applicant believes that such skill level is high. In any event, because the correct skill level necessarily impacts upon the evaluation of the other seven factors, a flawed analysis by the Examiner has resulted.

The Examiner has merely cited six of the seven above-mentioned Wands factors without appreciable analysis thereof. Such cursory treatment amounts to mere speculation and can be accorded no evidential weight in any attempt to establish a *prima facie* case of lack of enablement.

Regarding the sole Wands factor discussed in any detail by the Examiner in the outstanding Office Action – the required quantity of experimentation – the Examiner's opinion was that a large quantity of experimentation would be required to make and use the invention. The Hussain publication in Lancet was cited and relied upon by the Examiner to support the Examiner's opinion. This publication deals with rodent experiments, not with the practice of the claimed invention with

human patients, and thus Applicant does not consider the Lancet publication to constitute relevant evidence regarding enablement of the claimed invention. It is well known that the respective genetic makeups are not the same, and thus the Examiner's above-mentioned reliance upon such rodent publications appears to be inapt. In this regard, note the December, 2006 PlosOne publication entitled, "The Evolution of Mammalian Gene Families," authored by Jeffery P. Demuth et al. (hereinafter referred to as "Demuth" and attached hereto as Exhibit A). Demuth illustrates the fact that the respective gene families are distinct. Hence, one skilled in the art would not find the evidence proffered by the Examiner to be scientifically sound. Applicant further believes that the Examiner's reliance is misplaced when it is considered that the Examiner has proffered no evidence that rodent pancreas test results would translate to or correlate with a human pancreas. On the other hand, humans have been successfully treated in the claimed manner to achieve an improvement in pancreas function in a simple, routine manner without the need for large quantities of experimentation. In this regard, see the R.J. Fernandez et al. 2005 Late Abstracts The American Society for Cell Biology, 45th Annual Meeting, December 10-14, 2005 publication, entitled "First Reported Datas from Argentina of Implant and Cellular Therapy in Patients with Diabetes Type 2" (hereinafter referred to as "Fernandez"). The Fernandez publication was cited as Reference AV in the Supplemental Information Disclosure Statement filed by Applicant on June 14, 2006. In view of the above-discussed differences, Applicant believes that the Examiner should focus upon the Fernandez publication dealing with human patients rather than less relevant rodent publications such as Hussain. Should the Examiner continue to rely upon Hussain or like publications, Applicant believes that it is the burden of the Examiner to demonstrate why rodent studies constitute more relevant evidence than human studies when evaluating the enablement of a claimed invention

requiring a human patient. The Examiner is urged to consider Applicant's entire disclosure, as set forth above, in evaluating enablement because such disclosure is clearly more relevant than post-filing date publications. Applicant relies upon such disclosure rather than upon post-filing date publications. Once such disclosure is properly considered, there should be no remaining enablement issue.

Further, when considering that old administration techniques and materials are used in the claimed invention, there would be no need to conduct a large amount of experimentation. Rather, the highly skilled person in the medical art would find it straightforward to read and follow the disclosure contained in Applicant's specification, and thereby achieve the results of the claimed invention.

As a final point, the Examiner's attention is directed to the In re Wands decision, which led to the grant of a patent. The Court found that the PTO's determination of nonenablement was unsupported by the evidence in the record. In reversing the PTO, the Court specifically noted that the evidence in the record supported a finding of enablement. The Court further noted that the skill level in the art was high and that known materials were utilized in the practice of the invention in weighing the evidence. The instant fact situation is similar to that of In re Wands because the skill level is also high and known materials are also utilized in the practice of the invention. In addition to the factors considered in In re Wands, the administration techniques of the present invention are also old. Accordingly, the Examiner should be guided by the In re Wands decision and conclude that, based upon the disclosed invention, the claimed invention is enabled by the specification.

As is apparent from the above discussion of the Wands factors, the Examiner's conclusion that the disclosure is nonenabling is based upon speculation, not upon objective evidence. To

establish a *prima facie* case, the Examiner has the burden to present evidence doubting the objective enablement provided by Applicant's specification. It is well established that examiners are not experts in the art, and hence the Examiner's opinion is entitled to little, if any, weight. In re Neave, 370 F.2d 961, 152 USPQ 274 (CCPA 1967). It is clear that substantially more evidence than that provided by the Examiner in the present Office Action is required to establish a *prima facie* case of lack of enablement.

It is thereby submitted that because the Examiner has not made out the necessary *prima facie* case, the rejection under 35 U.S.C. §112, first paragraph, should be favorably reconsidered, withdrawn, and the application passed to issue.

Should the Examiner have any questions or require additional information or discussion to place the application in condition for allowance, a phone call to the undersigned attorney would be appreciated.

Respectfully submitted,

Date: February 6, 2007

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# EXHIBIT A

**December, 2006 PlosOne publication entitled,**
**"The Evolution of Mammalian Gene Families"**